REX MEDICAL
1100 E. Hector Street, Suite 245
Conshohocken, PA
19428

JUN - 1 2012

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA I990 and 21 CFR §807.92.

The assigned 510(k) number is: K120346

Submitter: Rex Medical, L.P.
1100 E. Hector Street, Suite 245
Conshohocken, PA 19428

Contact Person: Nicholas Ciccarelli
Design Engineer
Phone: (610) 940-0665 x109
Fax: (610) 940-1590
Email: nciccarelli@rexmedical.com

Date Prepared: February 1, 2012

Trade Name: Cleaner™ Rotational Thrombectomy System

Common Name: Peripheral Atherectomy Catheter (21 CFR 870.4875, Product Code MCW)

Predicate Device(s):

K091029	Cleaner™ Rotational Thrombectomy System
K060904	Cleaner™ Rotational Thrombectomy System

Device Description
The Cleaner™ Rotational Thrombectomy System is a 7F percutaneous mechanical thrombectomy catheter. It is a sterile, single use disposable device. Its handle contains a battery operated motor that spins a flexible "S" shaped guidewire at approximately 4000rpm. The wall contacting rotational wire, with integrated soft distal tip, permits atraumatic mechanical declotting of native vessel dialysis fistulae and synthetic dialysis access grafts. The wire creates a fluid vortex as it spins that macerates clot and allows it to be aspirated through the introducer sheath.

Intended Use:
The Cleaner™ Rotational Thrombectomy System is indicated for mechanical declotting of native vessel dialysis fistulae and synthetic dialysis access grafts.

Technological Characteristics:
The Cleaner™ Rotational Thrombectomy System is similar with regards to materials, intended use, principles of operation and technological characteristics to the predicate device. Results of

bench testing and animal studies demonstrate Cleaner™ Rotational Thrombectomy System is as safe and effective as the legally marketed predicate device.

Non-Clinical Performance Testing:
All testing performed on the Cleaner™ Rotational Thrombectomy System was derived from the risk assessment which evaluated the safety and effectiveness of the design modifications to the guidewire. Test methodology and acceptance criteria were derived from within Rex Medical and from related ISO standards for evaluation of this device.

Conclusion:
Rex Medical considers the Cleaner™ Rotational Thrombectomy System to be substantially equivalent to the predicate devices listed above. The conclusions are based on performance testing and similarities in indications for use, materials, technological characteristics, principle of operation and design features.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Rex Medical
c/o Ms. Susan Goldstein-Falk
mdi Consultants, Inc.
55 Northern Blvd., Suite 200
Great Neck, NY 11021

JUN - 1 2012

Re: K120346
Trade/Device Name: Cleaner Rotational Thrombectomy System
Regulation Number: 21 CFR 870.4875
Regulation Name: Intraluminal Artery Stripper
Regulatory Class: Class II (two)
Product Code: MCW
Dated: May 1, 2012
Received: May 4, 2012

Dear Ms. Goldstein-Falk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

REX MEDICAL
1100 East Hector Street, Suite 245
Conshohocken, PA 19428

Indications for Use

510(k) Number (if known): K120346

Device Name: Cleaner™ Rotational Thrombectomy System

Indications For Use:

The Cleaner™ Rotational Thrombectomy System is indicated for mechanical declotting of native vessel dialysis fistulae and synthetic dialysis access grafts.

Prescription Use X
(Part 21 CFR 801 Subpart D)

OR

Over-The Counter Use_____
(Part 21 CFR 801 Subpart D)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

M J Hillebran

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K120346